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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,033	KELLY-AEHLE, SANDRA	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 22-34* is/are pending in the application.

4a) Of the above claim(s) *7,8 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 9, 10 and 22-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed December 20, 2006 has been entered. Claim 1 has been amended. Claims 17-21 have been cancelled. Claims 7-8 and 11-16 have been withdrawn from consideration. Claims 1-6, 9-10 and 22-34 are under consideration in this office action.

Withdrawal of Rejections

2. The double patenting rejection has been withdrawn in view of applicants amendments and arguments.

Response to Arguments

3. Applicant's arguments filed December 20, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The rejection of claims 1-6 and 23-34 under 35 U.S.C. 103(a) as being unpatentable over Curtiss, III et al., (1996) in view of Peterson (4,449,968) is maintained.

The claims are drawn to a method of delivering a protein to a domestic bird comprising administering to the bird in a whole-body spray an effective amount of a avirulent derivative of an enteropathogenic bacterium comprising a recombinant gene that codes for the expression of the protein, wherein (a) the enteropathogenic bacterium is other than one that causes respiratory disease in birds, (b) the protein is delivered to the bird, and (c) the spray is composed of droplets having a mean diameter of 40-200 microns, wherein said live avirulent derivative of an enteropathogenic bacterium contains a mutation in a gene or genes selected from the group consisting of: *asd, thyA, phoP, cya, crp* and *cdt*.

Curtiss III et al., (1996) teach recombinant avirulent Salmonella vaccines for poultry. Numerous Salmonella serotypes are capable of infecting young chicks and the younger the chick the greater the susceptibility to infection (page 365). Salmonella can lead to a dose dependant transient lymphocyte depletion in the bursa of Fabricius and spleen with an induced impairment in immune responsiveness and enhancement in establishing a Salmonella carrier state (page 365-366). The objective was to minimize colonization of the intestinal tract and shedding by diverse Salmonella serotypes (page 366). The prior art teaches inoculation of avirulent Salmonella as live oral vaccines (page 366). A genetically altered avirulent *Salmonella typhimurium* vaccine strain for immunizing chicks and young pellets has been designed and constructed by the authors

(page 366). The live avirulent recombinant vaccine strains when used for oral immunization attach to, invade and colonize the gut-associated lymphoid tissue (GALT) where they continue to synthesize the foreign colonization or virulence antigen for several days to a few weeks (page 369). Curtiss III et al., teach the use of avirulent Salmonella as antigen delivery vector. In the system developed, the attenuated Salmonella vaccine strain has a chromosomal Δasd mutation eliminating the synthesis of B-aspartic semialdehyde dehydrogenase. The authors have constructed plasmid cloning vectors using the wild-type asd gene from either *S. mutans* or from *S. typhimurium* to complement the chromosomal Δasd mutation (page 369). The loss of the Asd+ plasmid causes DAPless death and cell lysis with release of foreign antigens (page 370). These deletion mutations were generated by transposon mutagenesis (page 366). Single immunization used 107 colony-forming units, (CFU) to induce protection to challenges (page 367). Immunization of chicks occurred on day-of-hatch, 3 days of age and 1, 2, 3, 4 and 14-20 weeks of ages with comparisons of single versus multiple immunizations and with doses ranging from 106 to 109 CFU (page 367). Young chicks immunized with one or two doses of the avirulent strain displayed a reduced ability to be colonized in the intestinal tract by virulent *S. typhimurium* strains (page 367). The avirulent *S. typhimurium* vaccine strain was administered as a coarse spray to newly hatched chicks and then administered in the drinking water to chicks 10 days of age or older (page 370). For chicks destined to become breeders or layers, a booster immunization should be administered at 14-18 weeks of age dependent on husbandry considerations (page 370). An anticipated immunization regime would be to vaccinate

breeders with the live avirulent strain followed by vaccination by coarse spray or in drinking water of the chicks from those breeders (page 370). Finally, infection with wild type virulent Salmonella can cause lymphocyte depletion with an impairment in immune responsiveness, thus the authors anticipate that birds hatched from eggs from immunized breeders and then immunized should display a more robust immune response and thus have a performance advantage over chicks that have never been immunized (page 371). Curtiss III et al., has been discussed above, however Curtiss III et al., do not teach using a coarse spray with specific droplet diameters.

Peterson teaches dosing the vaccine in a spray and spraying downward onto the chicks (col. 1, lines 47-50). Most of the spray droplets are of a size large enough to fall onto the chicks substantially without remaining airborne long enough to be inhaled by the chicks (col. 1, lines 50-53). Some of the droplets come to rest on other parts of the upper body portions of the chicks and the natural movements of the chicks tend to spread the droplets to the eyes of the chicks and to adjacent chicks (col. 1, lines 57-61). Furthermore, the chicks are inclined to peak at the droplets so the vaccine is received through the mouth of the chick (col. 1-2, lines 65-6). The poultry vaccination system can administer live vaccines to the chicks without handling each chick (col. 2, lines 20-22). The vaccine spray nozzles in combination with air pressure result in a large percentage of the vaccine being dispersed in droplets with diameter between 90 microns to 150 microns (co1.6, lines 40-43). The aerosol spray reliably administers vaccine to baby chicks without individual handling that prevents harm and without overdosing (col. 2, lines 18-27). Similar methods of administration are known in the art but several may

cause damage to the chicks or require time consuming techniques: de-beaking and eye dropper inoculations require the handling of each chick; spraying into the mouth may result in secondary infections and even death; and inhaling the vaccine resulted in chick lung diseases and sometimes death (col. 1, lines 20-40).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the method of Curtiss III, to use a poultry vaccination system as taught by Peterson since only routine skill would have been required to disperse droplets of 90-190 microns. One would have a reasonable expectation of success since only routine skill would be required to vaccinate the birds in a poultry vaccination system. Moreover no more than routine skill would have been required when Curtiss III, already teach using a coarse spray to orally deliver a vaccine for enteropathogenic bacterium while Peterson teach a preference that the spray droplets are large enough to fall onto the birds without remaining airborne long enough to be inhaled.

Response to Arguments

5. Applicants argue that Curtiss makes spray administration of the vaccine in the context of a transgeneration vaccination program. However the transitional phrases "comprising", define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d

1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."). Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Therefore, in view of the instant claim language being open and inclusive, the claims do not render the teaching of Curtiss' spray administration of the vaccine in the context of a transgeneration vaccination program as not teaching the claims. Furthermore, there is no limitation in the claim that prevents the vaccination scheme from being used within a transgeneration vaccination program. Moreover, Curtiss III et al., teach that chicks are immunized by coarse spray to display an enhanced immunity to prevent infection. Applicants have emphasized the fact that Curtiss III et al., teach a transgenerational vaccination program, however the method of delivery that applicants have claimed is the same method Curtiss III et al., uses. Moreover, the instant claims,

do not eliminate the delivery of a protein to domestic birds whose parents have also been vaccinated. Therefore applicants argument is not persuasive.

Applicants argue that there is no data on whole-body spray vaccinations and that Curtiss amounts to an invitation to conduct experiments. However, contrary to applicants' statements, Curtiss does more than invite experimentation. Curtiss provides an immunization schedule, provides a specific population, provides for days of immunization, the age of the chicks, routes of administration and dosage amounts, see page 367. Furthermore, an "anticipated" regime does not teach away from the instant claims. Curtiss III et al., state "It should be noted that the avirulent S.typhimurium vaccine strain χ3985 can be administered as a coarse spray to newly hatched chicks and then administered in the drinking water to chicks 10 days of age or older." Thus a skilled artisan has more than an invitation to experiment; Curtiss III et al., clearly recite a method for delivery. Thus applicants argument about the invitation to experiment is unpersuasive since applicants has neither alleged that experimentation is undue nor has applicant alleged that anything more the routine skill in the art is required when the prior art clearly tells a skilled artisan to administer the protein as a coarse spray.

Applicant argues that none of the examples in Curtiss demonstrate how a coarse spray is applied and that without a demonstration of effectiveness, the Examiner can not fairly contend that Curtiss teach the present invention. However, the MPEP section 2123 teaches that prior art is relevant for all they contain, the use of references is not limited to what the authors describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they

contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Here the reference is relied upon for teaching administration of the coarse spray vaccine. There is no requirement the Curtiss make a demonstration of how the spray is applied, rather the requirement is that Curtiss is relied upon for all that it would have reasonably suggested to one having ordinary skill the art, such as coarse spray administration. Therefore applicants' arguments are not persuasive and the rejection is maintained.

Applicants argue that the Curtiss reference to coarse spray do not specify a whole-body spray and that it is not possible to derive the teaching of Curtiss. However Curtiss, III et al., teach immunizing with avirulent enteropathogenic bacteria, i.e., a *S. typhimurium* vaccine strain administered as a coarse spray to newly hatched chicks followed by a booster administration in drinking water. See abstract and page 370. Vaccination equipment for administering coarse sprays are well known in the art, as admitted in the specification. Curtiss III et al., recite different terminology for other types of spray methods such as aerosol spraying, thereby differentiating the coarse spray from other spraying methods known in the art. Curtiss III et al., note the best immunization regime includes maternal immunization and further vaccination of chicks by coarse spray (page 370). Both the claims and specification define whole body spray

to encompass a coarse spray, thus Curtiss III et al., teach the limitations of the claims. Therefore Curtiss III et al., clearly teach administering coarse whole body spray. The coarse spray disclosed by Curtiss III et al., would be readily understood by the skilled artisan as evidenced by the prior art of record and admitted prior art, to mean a whole body spray of a particular range of droplet sizes and that techniques for applying coarse spray were well known in the art. Curtiss III et al., need not disclose all details of spray process in order to constitute an enabling reference, where the process is well known in the art. The specification admits that coarse spray equipment method was well known at the time the claimed invention was made.

Applicants argue that Curtiss does not disclose how the coarse spray is administered and does not describe what a coarse spray is. However, it should be noted that the claims do not define whole body spray to be anything more then a coarse spray of droplets. However, coarse spray is a term of art clearly understood by an artisan and defined by the specifications. There is no requirement that a reference must describe how a coarse spray is administered or the size of the droplets when the instant claims do not recite such limitations. Moreover, the specification teach the difference between aerosol sprays which spray very fine droplets or mist and are referred to as aerosol sprays and coarse sprays, and Curtiss III et al., distinguishes them one from the other, making clear the meaning of coarse spray as referred to by Curtiss III et al. Thus applicant's argument is unpersuasive since, no new and unexpected result has been achieved; the prior art already teaches the what a coarse spray is, since the instant specification teaches that whole body sprays can be coarse sprays.

Applicants argue that Peterson is directed to the administration of live virus vaccines for protection against respiratory diseases. In response to applicants' arguments against the Peterson reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The suggestion to administer enteropathogenic bacterial vaccines as a coarse spray is found in Curtiss III et al. Peterson is cited for the teaching that vaccination equipment and techniques for administering a coarse spray to the body of chicks were well established in the art and that a coarse spray was understood to be one in which droplets sizes in the range of 40-200 microns. Given the teaching of Curtiss et al., to deliver enteropathogenic bacterial vaccines as a coarse spray one would have been motivated to apply the vaccine using any well known method, such as that taught by Peterson and to apply the vaccine at the droplet diameter size range disclosed therein.

There does not appear to be any criticality to the droplet size recited in the claims insofar as vaccine efficacy is concerned in that they do not produce any new or unexpected results. In fact, the specification admits that the vaccination equipment used to apply the vaccines of the instant invention is not critical. Peterson teaches dosing the vaccine in a spray and spraying downward onto the chicks (col. 1 lines 47-50). Most of the spray droplets are of a size large enough to fall onto the chicks substantially without remaining airborne long enough to be inhaled by the chicks (col. 1 lines 50-53). Some of the droplets come to rest on other parts of the upper body

portions of the chicks and the natural movements of the chicks tend to spread the droplets to the eyes of the chicks and to adjacent chicks (col. 1 lines 57-61). Furthermore, the chicks are inclined to peak at the droplets so the vaccine is received through the mouth of the chick (col. 1-2 lines 65-6). Thus, the vaccine is received into the intestinal or mucosal lining. There would be a reasonable expectation of success when a well-known method of delivery as taught by Curtiss III et al., such as whole body coarse spray, to vaccinate chicks which would receive the vaccine through the mucosal lining as taught by Peterson. The use of a known method is not patentable distinct if the method is known to be useful for that purpose, even if the results are better then expected. No more than routine skill is involved in adjusting the amount of a composition of the claimed process to suit the particular method to achieve results taught in the prior art. *Mills et al., V Watson Comr. Pats.* (CADC 1955).223 F2d 335, 105 USPQ 355.

Applicants argue that Peterson teaches away from using claimed method of delivery. There is no evidence of record showing the administering a coarse spray of within a range of 40-200 microns cannot be achieved with the vaccination system of Peterson. Moreover, the system is clearly capable of administering droplets within the range of 40-200 microns as stated within the specification. Peterson's invention comprises administering a vaccine that is sprayed downward from the cabinet onto the chicks, where most of the spray droplets are of a size large enough to fall on to the chicks substantially without remaining airborne long enough to be inhaled by the chicks (col. 1 lines 43-55). Contrary to applicants arguments, the specification teaches that the

type of spray vaccination equipment used for the administration of the vaccine is not critical and almost any type of spray vaccination equipment capable of dispensing a coarse spray can be used, see for example US Patent 4,449,968, the Peterson references. Thus, in view of the instant specification, the Peterson system can administer droplets within the claimed range.

Applicants argue that neither Curtiss nor Peterson disclose a method of delivering a protein by "whole body spray". However, Curtiss III et al., clearly provide guidance for dosage amounts. Curtiss III et al., provide guidance to a skilled artisan as to a range for determining an effective amount colony forming units of bacteria. Moreover, the instant claims are drawn to the same range of colony forming units of bacteria. Furthermore, applicants have not supplied evidence to the contrary that the dosage schemes between the coarse spray and oral administration cannot be correlated to one another. Therefore, Curtiss III et al., clearly provide guidance for the specifically recited dosage ranges thereby providing a reasonable expectation of success. Applicants' arguments are not persuasive since the prior art provides guidance to enteropathogenic titers, a route of administration and droplet size as previously discussed; therefore a skilled artisan would have a reasonable expectation of success since the prior art teaches a method of delivery to a domestic bird comprising administering by whole body spray in an effective amount of vaccine comprising a live avirulent enteropathogenic bacteria to a bird. Accordingly applicants arguments are not persuasive.

6. The rejection of claims 9-10 under 35 U.S.C. 103(a) as being unpatentable over Curtiss, III et al., (1996) and Peterson (US Patent 4,449,968) further in view of Curtiss, III (US Patent 5,672,345) is maintained.

The claims are drawn to a method of delivering a protein to a domestic bird wherein the enteropathogenic bacteria is a derivative of a pathogenic strain of bacteria characterized by: a) a lack of a functioning native chromosomal gene encoding a first enzyme which is a B-aspartic semialdehyde dehydrogenase (Asd); b) the presence of a first recombinant gene encoding a second Asd enzyme wherein the first recombinant gene cannot recombine to replace the defective chromosomal gene; c) the presence of a second recombinant gene encoding a desired polypeptide; and d) physical linkage between the first recombinant gene and the second recombinant gene, wherein loss of the first recombinant gene causes the bacteria to lyse when in an environment which requires expression of the first recombinant gene for cell survival, or wherein the enteropathogenic bacteria are selected from the group of strains consisting of X6097 (ATCC 67537), X3520 (ATCC 53681), 7~4072 (ATCC 67538), 7~3008 (ATCC 53680), X2108 (ATCC 53678), and X6097 (ATCC 67813). Curtiss III (1996) and Peterson have been discussed above, however neither teach the specific derivative of the pathogenic strain of bacteria. Curtiss, III teach materials and methodologies for preparing vaccines and recombinant DNA expression products to genetically engineered microorganisms which are useful to express desired gene products because they balance lethals which can be maintained in a genetically stable population (col. 1, lines 20-25). The invention

teaches maintaining a desired recombinant gene comprising growing genetically engineered cells characterized by: a) a lack of a functioning native chromosomal gene encoding a first enzyme, which is essential for cell survival, wherein the first enzyme catalyzes a step in the biosynthesis of an essential cell wall structural component; b) the presence of a first recombinant gene encoding an second enzyme which is a functional replacement for the first enzyme, wherein said first recombinant gene cannot replace the defective chromosomal gene; c) the presence of a second recombinant gene encoding a desired polypeptide; and d) physical linkage between the first recombinant gene and the second recombinant gene, wherein loss of the first recombinant gene causes the cells to lyse when the cells are in an environment where a product due to the expression of the first recombinant gene is absent (col. 4, lines 35-53). The invention teach that there is a mutation in a gene encoding B-aspartic semialdehyde dehydrogenase (Asd) (col. 5, lines 1-4). The patent states that a deposit of the cultures was made to ATCC, wherein the deposits are ;(6097 (ATCC 67537), ;~3520 (ATCC 53681), X4072 (ATCC 67538), 7~3008 (ATCC 53680), ~2108 (ATCC 53678), and X6097 (ATCC 67813) (col. 23, lines 15-25). Thus, these deposited strains are the same instantly claimed deposits, to thereby meet the limitations of the claims. The cells of the invention are useful for commercial production of desired products, for components of vaccines for immunizing individuals, and for release into the environment. An "individual" treated with a vaccine of the invention is defined herein as including mammals, and various species of birds, including domestic birds, just as required by the claims (col. 7, lines 57-61). Administration of a live vaccine of the type disclosed above

to an animal may be by any known or standard technique (col. 21, lines 20-21). These include oral ingestion, gastric intubation, broncho-nasal spraying or in forms of aerosols (col. 20, lines 43-46). All of these methods allow the live vaccine to easily reach the GALT or BALT cells and induce antibody formation (col. 21, lines 26-29).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the method of Curtiss III et al., and Peterson, to use the enteropathogenic bacteria are selected from the instantly claimed group as taught by Curtis, III since only routine skill would have been required to exchange the enteropathogenic bacteria comprising the recited gene when the prior art already teach the asd gene's usefulness for delivering proteins to domestic birds. One would have a reasonable expectation of success since only routine skill would be required to vaccinate the birds using a well known gene and strains of bacteria known in the art to be capable of delivery proteins. Moreover no more than routine skill would have been required when Curtiss III et al., already teach using a coarse spray to orally deliver a vaccine for enteropathogenic bacterium while Curtis, III teach administration via oral ingestion or by aerosol spray when aerosol and oral vaccination is a well known and popular technique to deliver birds droplets within the instantly claimed ranges.

Response to Arguments

7. Applicants urge that Curtis '345 does not teach the effectiveness of the whole-body spray for delivery of a protein to poultry via a bacterial vector. However, there is no requirement that Curtiss teach the effectiveness of the method of delivery. However, the

MPEP section 2123 teaches that references are relevant as prior art for all they contain, the use of references is not limited to what the authors describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Here the reference is relied upon for teaching administration of the coarse spray vaccine. There is no requirement the Curtiss make a demonstration the effectiveness of the spray vaccine, rather the requirement is that Curtiss is relied upon for all that it would have reasonably suggested to one having ordinary skill the art, such as coarse spray administration. Furthermore, Curtiss provides an immunization schedule, provides a specific population, provides for days of immunization, the age of the chicks, routes of administration and dosage amounts. Thus applicants argument is unpersuasive since applicants has not alleged that anything more the routine skill in the art is required when the prior art clearly tells a skilled artisan to administer the protein as a coarse spray.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary

skill in the art would have a reasonable expectation of success since only routine skill would be required to vaccinate the birds using a well known gene and strains of bacteria known in the art to be capable of delivery proteins. Furthermore, no more than routine skill would have been required when Curtiss III et al., already teach using a coarse spray to orally deliver a vaccine for enteropathogenic bacterium and Curtiss, III teach administration via oral ingestion or by aerosol spray when aerosol and oral vaccination is a well known and popular technique to deliver birds droplets within the instantly claimed ranges. Therefore the rejection is maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
March 16, 2007

MARK NAVARRO
PRIMARY EXAMINER